REMARKS

The Office Action dated May 6, 2009, addresses claims 31, 34-37, 40-42 and 60-63 rejecting all claims under 35 U.S.C. § 103(a). Claims 31, 34-35 and 60-63 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nobles (U.S. Publication No. 2002/0045908, which issued as U.S. Patent No. 6,562,052, "Nobles") in view of Ginn et al. (U.S. Patent No. 6,702,835, "Ginn"). Claim 36 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nobles in view of Ginn and further in view of Sawyer (U.S. Patent No. 5,749,895, "Sawyer"). Claim 37, 40 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nobles in view of Ginn and further in view of Das (U.S. Patent No. 5,334,217, "Das"). Claim 42 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nobles in view of Ginn and Das and further in view of Sawyer.

For all of the following reasons, Applicants respectfully request reconsideration and early allowance of the pending claims.

Rejection of claims under 35 U.S.C. § 103(a)

Applicants respectfully traverse the rejection of claims 31, 34-37, 40-42 and 60-63 under 35 U.S.C. § 103(a) as being unpatentable over Nobles in view of one or more of the Ginn, Das and Sawyer references. Applicants respectfully submit that the proposed combination of the Noble, Ginn, Das and Sawyer references fail to support a *prima facie* case of obviousness under 35 U.S.C. § 103. As set forth in the MPEP, to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the Office bears the burden of establishing each of three requirements. First, the references must teach or

suggest each and every element and limitation recited in the claims. *See* M.P.E.P. § 2143.03. Second, the Office must establish that some suggestion or motivation exists, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references to achieve the presently claimed invention. *See* M.P.E.P. § 2143.01. Third, the Office must establish a reasonable expectation of success for the proposed combination. *See* M.P.E.P. § 2143.02. In the present case, Applicants assert that independent claims 31 and 37 recite at least one limitation that is not taught, disclosed or suggested by Noble, Ginn, Das and Sawyer, either alone or in combination.

Independent claim 31 recites at least the limitations "introducing into a heart of a patient a delivery member comprising at least a first flexible member, said first flexible member comprising a first end portion and a second free end portion" and "introducing said second free end portion of said first flexible member through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through a septum primum," which are not taught, disclosed or suggested by Nobles. Applicants respectfully submit that Nobles neither discloses, teaches or suggests a flexible member for tissue stabilization, nor does Nobles disclose, teach or suggest that any portion of his suturing device is capable of being deployed through the tunnel of a patent foramen ovale (PFO).

The Examiner equates the first flexible member, as recited in claim 31, to the actuation rod or wire 50 of Nobles. *See* Office Action at Page 2. As described in col. 10, l. 53-58 of Nobles, the actuation rod 50 is connected to an actuation assembly 170 at a proximal end (first end portion) and suture clasp arms 28, 30 at the distal end (second end portion). First, Applicants respectfully point out that the actuation rod 50 does not comprise a flexible member capable of traversing the tunnel of a patent foramen ovale, as recited in claim 31. Nowhere does Nobles disclose or suggest that actuation rod 50 has a flexible structure or configuration. Second, even assuming *arguendo* that the actuation 50 is flexible, Nobles does not disclose, teach or suggest that the actuation rod 50 passes through the tunnel of the PFO from the right atrial side to the left atrial side, nor is it capable of such.

In the outstanding Office Action, the Examiner refers to col. 9, l. 64 to col. 10, l. 4 of Nobles (¶[0141] of the published application) which describes that the suturing device could be used for suturing a PFO. *See* Office Action at p. 3. Without acquiescing to the Examiner's assertions, Applicants respectfully point out that even if Nobles' suturing device could be used for suturing a PFO, nowhere does Nobles disclose, teach or suggest that a flexible member of the suturing device is deployed through the tunnel of the PFO to stabilize the septum primum while introducing a hole therethrough. In all the embodiments described in Nobles, the opening or defect 26 is coplanar with the surface of the tissue 22. Whereas, in the case of a PFO, the opening or hole is in the form of a tunnel between the left and right atria comprising of two layers of partially overlapping but unfused cardiac tissue. *See* ¶[0004] of the present application. Applicants respectfully submit that due to the oblique tunnel-like nature of many PFOs, the suture

clasp arms 28, 30 will not be suitable or capable of traversing the PFO, and sit flush with the septal wall to provide mechanical support while puncturing the tissue. Therefore, Applicants respectfully submit that at least the limitations "introducing into a heart of a patient a delivery member comprising at least a first flexible member, said first flexible member comprising a first end portion and a second free end portion" and "introducing said second free end portion of said first flexible member through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through a septum primum," of claim 31 are not taught, disclosed or suggested by Nobles.

Ginn, which the Examiner cites only with regards to the direction of tissue penetration, does not overcome this deficiency of Nobles. In particular, Applicants respectfully point out that Ginn simply teaches advancing a needle though the septal wall from the right to the left atria. Nowhere does Ginn disclose, teach or suggest advancing a flexible stabilization member through the tunnel of a PFO from the right atrium to the left atrium prior to introducing a hole in the septal wall. Therefore, Applicants respectfully submit that claim 31 is patentable over Nobles in view of Ginn. Claims 34, 35 and 60-63 depend from claim 31, and therefore, are patentable over Nobles in view of Ginn for at least the same reasons as claim 31.

Claim 36, which also depends from claim 31, is rejected as unpatentable over Nobles in view of Ginn and further in view of Sawyer. Sawyer, which the Examiner has

cited only with regard to a tissue welding apparatus, does not overcome the deficiencies of Nobles and Ginn. Therefore, claim 36 is patentable over Nobles in view of Ginn and further in view of Sawyer for at least the same reasons as claim 31.

Similarly, independent claim 37 recites at least the limitations "introducing into the heart of a patient a delivery member for delivering a plurality of hexagonally shaped flexible members" and "introducing at least one of said hexagonally shaped flexible members through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through a septum primum," which are not taught, disclosed or suggested by Nobles. As described earlier, Nobles and Ginn, either alone or on combination, do not disclose a flexible member capable of traversing through the tunnel of a PFO from the right atrium to the left atrium. Das, which the Examiner has cited only with regard to a hexagonally shaped occlude, does not overcome the deficiency of Nobles in view of Ginn. In particular, Applicants point out that the claim 37 recites a hexagonally shaped flexible member, and not a hexagonally shaped occuler as disclosed by Das.

For at least the above reasons, Applicants respectfully submit that independent claim 37 is patentable over Nobles in view of Ginn and further in view of Das. Claims 40 and 41 depend from claim 37, and therefore, are patentable over Nobles, Ginn and Das for at least the same reasons as claim 37. Claim 42, which also depends from claim 37, is rejected as unpatentable over Nobles in view of Ginn and Das and further in view of

Sawyer. As discussed earlier, Sawyer does not overcome the deficiencies of Nobles, Ginn and Das. Therefore, claim 42 is patentable over Nobles in view of Ginn and Das and further in view of Sawyer for at least the same reasons as claim 37. Applicants respectfully request that the rejection of claims 31, 34-37, 40-42 and 60-63 under 35 U.S.C § 103(a) be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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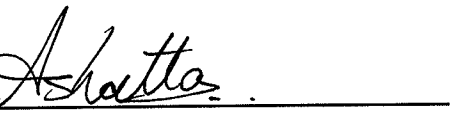
Dated: February 23, 2010

By: 
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